

### REMARKS/ARGUMENTS

Claims 1-20, 54 and 55 were examined, with all other claims having been withdrawn pursuant to a restriction requirement. The claims have been amended and cancelled as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

Applicants thank Examiner Neal for the courteous and helpful interview on September 6, 2006. As discussed at the interview, all independent claims have been amended to recite that a helical fold line extends over the entire length of the balloon from the proximal end to the distal end. The nature of the groove in claim 15 was also discussed and is clarified below.

All claims were rejected as being anticipated by U.S. Patent No. 5,792,415 to Hijlkema optionally in combination with U.S. Patent No. 6, 468,243 to Miyagawa et al., US2002/0077606 to Trotta, U.S. Patent No. 4,276,874 to Wolvek et al., and US2002/0151924 to Shiber. Such rejections have been overcome by amending independent claims 1, 15 and 54 to clearly distinguish teachings of Hijlkema '415.

The present invention is directed at angioplasty and similar balloon catheters having permanent fold lines formed in their outer surfaces to facilitate both initial folding, and more importantly to facilitate deflation and collapse within the vasculature after use. As well-described in the specification and illustrated in Fig. 1, the fold lines 22 clearly extend from the distal end 16 of the balloon to the proximal end 18 over the entire length of the balloon. Having the fold lines extend over the entire length of the surface of the balloon is the most effective way of causing the balloon to collapse into the helical lobes or flaps, as shown in Fig. 4 of the present application.

The Hijlkema '415 patent does not describe imparting fold lines into the balloon at all. Instead, the '415 patent teaches that by twisting the balloon of the balloon catheter while it is being molded, certain spiral ridges of material (also given reference no. 22) will be "formed in

the transition sections 11 extending spirally inwardly from the end sections 12." See, col. 3, lines 51-59 referring to Fig. 3 of the drawings. These ridges then act as the "spokes of an umbrella" when the balloon is folded. The ridges, however, as specifically taught to not extend over the central section and thus do not cover the entire length of the balloon, as required by all claims in the present application, as now amended.

The teachings of Miyagawa et al. '243 are similar, where a balloon is twisted to cause a spirally lobe configuration when the balloon is inflated. There is no remote teaching in Miyagawa, however, at providing any fold lines in the surface of the balloon or elsewhere to achieve such an inflation pattern. Instead, this pattern is achieved merely by rotationally offsetting the two ends of the balloon when they are attached to the balloon shaft.

The teachings of the remaining secondary patents are even less pertinent. While Trotta teaches "a groove" in a balloon, this groove is formed by constricting the inflated balloon with a helical wire as is intended to permit blood perfusion (§ 33), not to cause folding of the balloon. Nor is the "groove" of Trotta permanently formed in the outer surface of the balloon as now required by claim 15. Instead, Trotta teaches forming a temporary channel only when the balloon is inflated. Thus, even if combined with Hijlkema, the permanent groove fold lines of claim 15 would not be taught. There would have been no motivation to combine such a teaching with the primary teachings of Hijlkema or any other of the references herein.

Wolvek et al. '874 merely teaches that balloons may be folded into flaps, and provides no suggestion that such a result should be achieved through the use of fold lines formed over the entire length of the surface of the balloon.

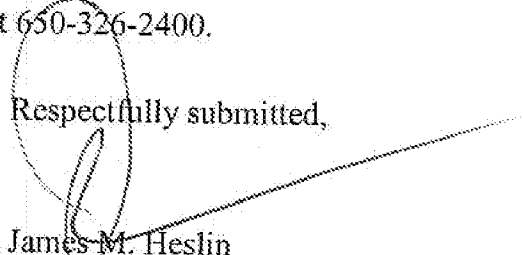
Shiber teaches scoring elements enveloping in the balloon. The balloon of Shiber, however, does not have the fold lines formed in the outer surface of the balloon. Instead, the balloon folding pattern is caused by the scoring structure of Shiber.

Independent claims 1, 15, and 54 have been amended to clarify the distinctions discussed above. In particular, each of these claims has now been amended to require that the fold line extend over at least the middle portion of the balloon (claim 1) or over the entire balloon length (claims 15 and 54). Each of these requirements clearly distinguish the teachings of Hijlkema even when combined with any of the secondary references.

Based on the above amendments and remarks, Applicants believe that all pending claims are in condition for allowance and request that the application be passed to issue at an early date.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

  
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